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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/803,918

03/19/2004

Torbjorn Hjam

150-149

6704

7590

02/14/2006

Steven S. Payne
8027 ILIFF Drive
Dunn Loring, VA 22027

EXAMINER

YUN, JURIE

ART UNIT

PAPER NUMBER

2882

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/803,918

Applicant(s)HJARN, TORBJORN **Examiner**

Jurie Yun

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 12/12/05 has been entered.

Specification

2. The disclosure is objected to because of the following informalities: on page 5, line 14, there is no period at the end of the sentence. Appropriate correction is required.
3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: there is no teaching in the specification for the "container being arranged to expand into an inclined configuration having a lower and a higher section, said lower section being closest to the body of the person during examination" as claimed in new claim 17, and a "compression surface being inclined with respect to the support arrangement in the actuated configuration thereby providing a greater breast-receiving space for the base of a breast than the distal end of the breast" as claimed in new claim 32, and similarly for new method claim 35.

Claim Objections

4. Claim 29 is objected to because of the following informalities: there appears to be a typo in that "configured control" should perhaps read "configured to control". Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. Claim 31 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it

pertains, or with which it is most nearly connected, to make and/or use the invention.

There is no teaching for how "the container is filled with a temperature-adjusted medium tailored for the examined person's comfort." There is no description in the specification as to how this is done, as well as no structural means for doing this.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

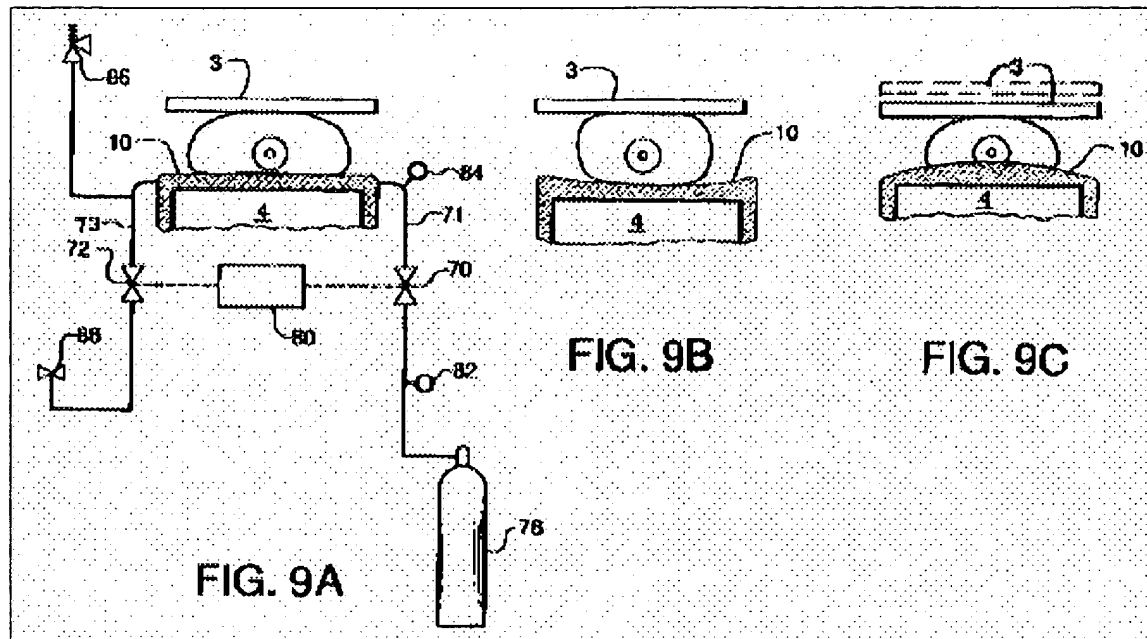
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 17-24 and 26-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Galkin (USPN 6,850,590 B2) in view of Livingston (US 2005/0008117 A1).

8. With respect to claims 17 and 32-35, Galkin discloses a pressurizing arrangement in a mammography equipment piece that is configured to provide a well defined and comfortable positioning and fixation of a human breast of an examined person and wherein the mammography equipment piece includes an x-ray source (Fig. 1, 1) and an examination area for the breast, as well as an upper and a lower compression plate (Fig. 9A - 3 & 4), said pressurizing arrangement comprises: an essentially elastic container (10) constructed of an x-ray permeable material and configured to be located within the examination area between the upper and lower compression plates, said elastic container comprising an inlet (71) for receiving a

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medium which expands the container and presses the breast against an oppositely positioned compression plate (Figs. 9B & 9C).

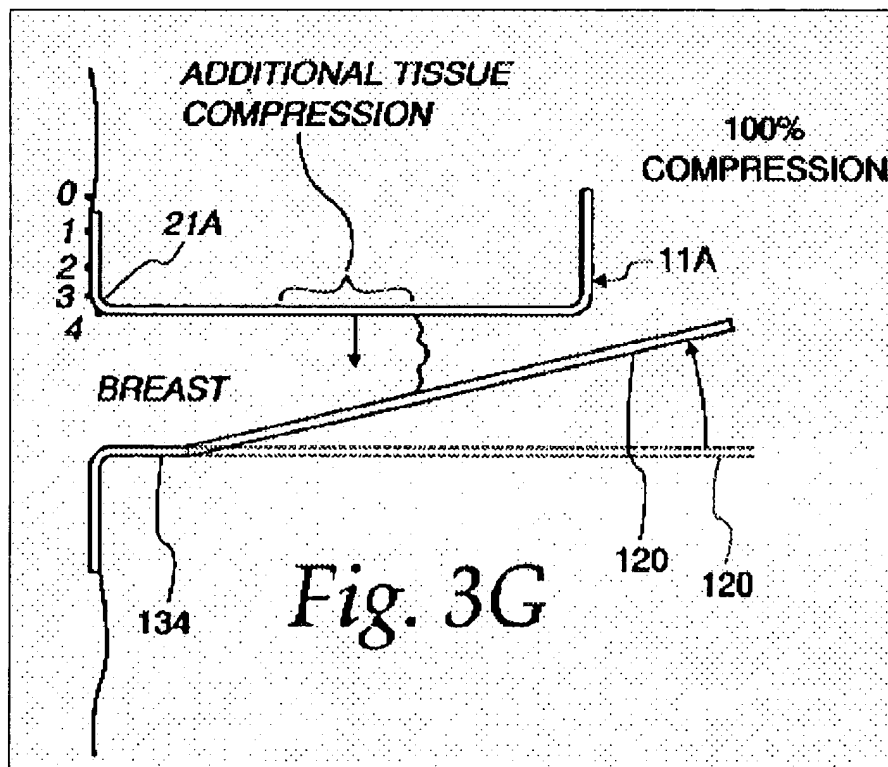


Galkin does not disclose the container being arranged to expand into an inclined configuration having a lower and a higher section, said lower section being closest to the body of the person during examination. Livingston teaches (paragraph 0010), "Now there has been a general recognition that good and more uniform compression is most desirable in mammography systems, as also a recognition that the proposed systems should address the issue of less patient's discomfort because many of the patient's find the mammography operation to be painful." To solve these problems, Livingston discloses (paragraph 0018):

[0018] In accordance with a preferred embodiment, there is provided an improved method and apparatus for **compressing substantially the posterior breast at a location adjacent the chest wall** and to stabilize this tissue while in a compressed state without pushing of the posterior breast tissue back into the chest wall and from the imaging area, **and then to compress the middle and anterior tissue with an inclined portion providing a substantial compression of the middle and anterior**

breast over a wide range of sizes, shapes and densities of breasts without an interfering shadow in the imaging area and without pushing the posterior tissue back into the chest wall and from the imaging area. Preferably, this is achieved by a patient and operator user-friendly method with less discomfort to the patient. By way of an example only, the initial compression of the posterior breast tissue at the chest wall between the paddle and bucky is achieved by the paddle traveling downwardly through about six centimeters without the patient feeling any significant discomfort; and then rather than displacing the paddle vertically relative to the bucky where the patient feels significant discomfort and/or pain, the posterior ends of the bucky and paddle remain at this 6 centimeter displacement and an inclined portion on the paddle or bucky is swung to compress the middle and anterior breast portions.

Figure 3G depicts this:



It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Galkin elastic container (10) to assume the shape during imaging taught by Livingston, to provide for better image quality as well as to provide for patient comfort. Livingston teaches that this configuration for compressing the breast

causes little discomfort or pain even though there may be 90 or 120 newtons of force applied at the posterior breast tissue (paragraph 0026).

With respect to claim 18, Livingston teaches a contact surface between the container and the breast exhibits a receiving space such that a compression force is essentially uniformly distributed on the breast (paragraph 0030).

With respect to claim 19, Galkin discloses the container forms a pillow positioned on the lower compression plate in the examination area (see Fig. 9A above).

With respect to claim 20, Galkin discloses a contact surface of the container substantially surrounds the breast (see Fig. 9A above).

With respect to claim 21, Galkin discloses the container is made from one of (1) a fabric material, (2) a polymer material and (3) a rubber material (column 6, lines 7).

With respect to claim 22, Galkin discloses the medium which expands the container is gaseous (column 10, line 3).

With respect to claim 23, Galkin discloses the medium which expands the container is air (column 10, line 4).

With respect to claim 24, Galkin discloses the medium is a fluid (column 9, lines 62+).

With respect to claim 26, Galkin discloses conduits (71 & 73) attached to the container (10) for conveying medium to at least one inlet and from at least one outlet of the container.

With respect to claim 27, Galkin discloses at least one inlet of the container is attached to a controllable medium compressor (80 & 82 & 84).

With respect to claim 28, Galkin discloses the outlet (73) accommodates evacuation of medium from the container (10).

With respect to claim 29, Galkin discloses a measuring and control apparatus configured to control the compression force exerted on the breast based on measured pressure in the container (column 10, lines 9+).

With respect to claim 30, Galkin in view of Livingston does not disclose a display unit for displaying the measured pressure inside the container. However, Galkin teaches pressure reading means (column 10, lines 9+) and it would have been obvious to one of ordinary skill in the art at the time the invention was made that the Galkin apparatus includes some means for displaying the pressure which is monitored by the pressure reading means for control over the examination.

With respect to claim 31, Galkin in view of Livingston does not disclose the container is filled with a temperature-adjusted medium tailored for the examined person's comfort. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to do this, to provide for additional comfort during the examination. Galkin and Livingston are concerned with patient comfort, and this would be an obvious modification.

9. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Galkin (USPN 6,850,590 B2) in view of Livingston (US 2005/0008117 A1) as applied to claims 17 and 24 above, and further in view of Redington et al. (USPN 3,973,126).

10. With respect to claim 25, Galkin in view of Livingston does not disclose the medium is water. Redington et al. teach that water is a good medium for surrounding a breast undergoing tomographic examination (column 3, lines 12-17). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use water as the medium in the Galkin apparatus, because it has an x-ray absorption coefficient relatively close to that of soft human tissue, as taught by Redington et al., to increase image resolution.

Response to Arguments

11. Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection to the newly added claims 17-35.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jurie Yun whose telephone number is 571 272-2497.

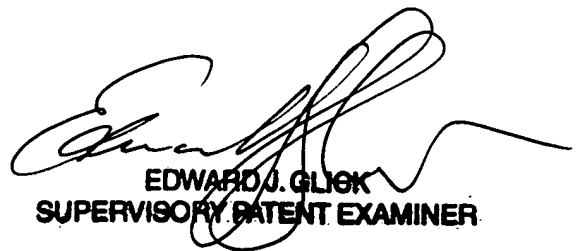
The examiner can normally be reached on Monday-Friday 8:30-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ed Glick can be reached on 571 272-2490. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jurie Yun
February 7, 2006



EDWARD J. GLICK
SUPERVISORY PATENT EXAMINER